CHPA
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Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Formerly Nonprescription Drug Manufacturers Association

November 5, 1999

Docket Management Branch (99N-4235)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99N-4235: Agency Emergency Processing Under OMB Review; Survey of Manufacturing Practices in the Dietary Supplement Industry

TO WHOM IT MAY CONCERN:

The Consumer Healthcare Products Association (CHPA) is submitting these comments, in response to the Food and Drug Administration (FDA) notice that appeared in the October 6, 1999 issue of the Federal Register (Volume 64, Number 193). In this notice, FDA is proposing to conduct a survey of manufacturing practices of dietary supplement establishments. The objectives of this survey, as stated, are to help FDA learn about the existing practices and to help formulate a policy to ensure that dietary supplements are produced under conditions that will minimize safety problems resulting from manufacturing without imposing unnecessary costs to the industry. The survey will also provide FDA with an understanding of the economic impact that any proposal to establish current good manufacturing practice (CGMP) regulations will have on both large and small firms in the dietary supplement industry.

CHPA is a 118-year-old trade organization representing producers of quality nonprescription medicines and dietary supplements. CHPA has over 200 members across the manufacturing, distribution, and service sectors of the self-care industry.

As indicated in comments filed with FDA on September 30, CHPA would like to see CFSAN place publication of ANPR for dietary supplement GMPs as a top priority in 2000. In addition, as communicated at the meeting on June 30, 1999, between members of CHPA's Dietary Supplements Strategic Planning Group and CFSAN, CHPA would like to assist FDA with the development of these GMPs. At this meeting, CFSAN explained that

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site visits to DS manufacturing facilities would help the agency in its development of a proposed rule on GMPs. In response to this request, four CHPA member companies agreed at the meeting to work with CFSAN in organizing site visits to their facilities. These site visits took place in September 1999 and from feedback we received, the experience was very productive for both FDA and our member companies.

In regard to the proposed FDA survey of manufacturing practices in dietary supplement establishments, at the request of CHPA we received a copy of this survey and draft supporting statement from Peggy Schlosburg at the FDA. Having read the survey and draft supporting statement, we are of the opinion given the nature of some questions in the survey, manufacturers may choose not to respond rather than turn in an incomplete survey. Because of this action, FDA may not get the response it is expecting; i.e. 400 completed surveys or a 55% response rate. To encourage CHPA members to provide feedback to FDA on it's October 6 Federal Register notice and survey, we mailed a copy of the survey and draft supporting statement to members representing the dietary supplement industry.

In conclusion, as indicated in comments CHPA filed with FDA on CFSAN's program priorities for the year 2000, we would like to see CFSAN place safety first – enforcement, GMPs and AERs when setting its priorities for program activities in the year 2000. Specifically, publication of ANPR for dietary supplement GMPs and having in place an effective and visible enforcement program. Further, rather than provide for special allowances for small firms in the dietary supplement industry in the GMPs for dietary supplements, we recommend that FDA extend the date by which these companies should comply with the regulation. Again, CHPA would like to extend its hand to assist FDA in drafting the proposed rule for dietary supplement GMPs. Please do not hesitate to contact either of us should FDA require additional assistance in refining the draft GMPs for dietary supplements.

Sincerely yours,

R. William Soller (ln)

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Director of Science & Technology

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